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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,980	07/17/2000	RICHARD KOLESNICK	D6049	6671

7590 06/24/2003  
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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

# Office Action Summary

Application No.

09/554,980

Applicant(s)

KOLESNICK ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **Detailed Office Action**

1. Receipt of Applicants' arguments and amendments filed in Paper No.15 on 24 March 2003 is acknowledged. Claims 1, 4 and 10 have been amended. Thus claims 1-4, 6-7 and 10 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.14, 03/24/03:

(I) The rejection of claims 1, 2 and 3 made under 35 U.S.C. 112, second paragraph.

(II) The rejection of claims 1, 4 and 10 made under 35 U.S.C. 102(b) as being anticipated by Fuks et al (1994), because amended claims 1, 4 and 10 are not anticipated by Fuks et al, since this reference does not teach a method of treating endotoxic shock or sepsis by administering b-FGF to an animal that has endotoxic shock or sepsis.

(III) The rejection of claims 1, 2, 3, 4, 6 and 7 made under U.S.C. § 103 as being unpatentable over Fuks et al (1994).

(IV) The rejection of claims 4-7 and 10 are rejected under 35 U.S.C. 112, first paragraph.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 U.S.C. § 102***

4. Claims 4, 6, 10 stand rejected and amended claim 1, (as well as claim 2) are also rejected under 35 U.S.C. 102(e) as being anticipated by Jain et al. (U. S. Patent

Art Unit: 1647

6,010,712), for reasons of record set forth in the office action mailed on 13 December 2002, in paper No:13, pages 8-9.

Applicants argue that Jain et al do not anticipate instant claims 4, 6 and 10, because they do not teach inhibition of endothelial cell apoptosis in order to treat endotoxic shock or sepsis. Applicants also argue that Jain et al provide no teachings or examples linking the modulation of CAM expression by b-FGF to the inhibition of apoptosis in endothelial cells, nor do they show that the administration of b-FGF would effectively treat endotoxic shock or sepsis. Finally, Applicants submit that Jain et al only teach that b-FGF decreases the cell surface expression of at least one of ICAM-1, VCAM and E-selection of endothelial cells, thereby decreasing adhesion of cytotoxic white cells to vascular endothelium. Therefore, Applicants conclude that all the elements of the present claims are found among the teachings of Jain et al.

These arguments have been fully considered but are not deemed persuasive. Jain et al disclose a method of treating sepsis by administering b-FGF to an animal suffering from said condition. Instant claims 1, 4, 6 and 10 are drawn to a method of treating endotoxic shock or sepsis in an animal (human) by administering b-FGF to said animal, wherein said animal has endotoxic shock or sepsis. Therefore, the Jain et al reference teaches treating the same population as instant claims and using the same compound (namely b-FGF). Whether the mechanism of action is the inhibition of endothelial cell apoptosis or decreasing the cell surface expression of at least one of ICAM-1, VCAM and E-selection of endothelial cells in order to treat endotoxic shock or sepsis, is irrelevant, because both the Jain et al reference and instant claims 1, 4, 6 and

Art Unit: 1647

10 teach treating the same population suffering from the same condition with the same composition. Finally, Jain et al do show that the administration of b-FGF effectively treats sepsis, (see claims 1 and 2).

***Claim Rejections - 35 USC § 103***

5. Claims 4, 7 stand rejected and also claims 1 and 3 are rejected under U.S.C. § 103 as being unpatentable over Jain et al is maintained for reasons of record set forth in the office action mailed on 13 December 2002, in paper No:13, pages 9-10.

Applicants argue that Jain et al teach use 30 µg of b-FGF per mouse, a dosage that is an order of magnitude higher than the dose taught in the instant specification, which is 800 ng of b-FGF per mouse (see page 9, lines 25). Therefore, Applicants contend that the *in-vivo* b-FGF dosage taught by Jain et al does not suggest the much lower dose employed in the present application.

This argument is not found persuasive, because, applicants are arguing limitations not recited in the claims. Instant claims 3 and 7 recite 0.1 mg/kg to 100 mg/kg, a range that is much higher than the 800 ng per mouse that Applicants are arguing. The upper limit dose (i.e 100 mg/kg) recited in claims 3 and 7 is much higher than the dosage disclosed by Jain et al.

Therefore, it would have been obvious to use the dosage range recited in instant claims 3 and 7, from the teachings of Jain et al, because the optimal dosage for a given patient depends upon weight, age and gender and can be determined by one of ordinary et al in the art.

Art Unit: 1647

**Conclusion**

6. No claim is allowed.
7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
June 19, 2003

  
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